REMARKS

I. Amendments

A. Claims

Claims 1-4, 11, 13-16 and 21-25 have been canceled, as drawn to a non-elected invention. Further, claims 37-40 have been cancelled. Claims 26, 31 and 34 have been amended. The amendments to the claims do not add or constitute new matter, and are completely supported by the application as originally filed. Support may be found throughout the specification and in the originally filed claims. Specifically, support for the amendments to claims 26, 31 and 34 may be found, for example, at page 48, line 9 through page 49, line 14, of the specification.

The amendments to the claims are made without prejudice to the pending or now canceled claims or to any subject matter pursued in related applications. Moreover, the amendments are made solely to expedite prosecution of the application and are not intended to limit the scope of the invention. The Applicant reserves the right to prosecute any canceled subject matter at a later time or in a later filed divisional, continuation or continuation-in-part application.

B. Drawings (Sequence Compliance)

The Examiner has noted that the instant application allegedly fails to comply with the requirements of 37 CFR 1.821 through 1.825, in particular because the sequence disclosed in Figure 2A lacks a sequence identifier. Applicant agrees with the Examiner's conclusion that a sequence identifier was inadvertently omitted, and that the sequence disclosed in Figure 2A is the nucleotide sequence set forth in SEQ ID NO:1. Applicant has submitted a new Figure 2A which properly identifies the sequence, and believe they are in compliance with 37 CFR 1.821 through 1.825. Applicant submits that no new matter has been added by this amendment.

II. Rejections

A. Rejections under 35 U.S.C. § 101

Claims 26-40 were rejected under 35 U.S.C. § 101, because, according to the Examiner, the claimed invention is not supported by either a credible asserted utility or a well established utility. The Applicant respectfully traverses this rejection.

Specifically, the Examiner states that the instant specification asserts the utility for the transgenic mouse embraced by the claims is for screening agents that may affect a phenotype of the mouse. The instant specification has disclosed that the phenotype of the mice of the present

invention is increased prepulse inhibition. However, the Examiner alleges that the evidence of record does not provide a correlation between increased prepulse inhibition and any disease or disorder. Further, the Examiner notes that the evidence of record fails to provide a correlation between any ubiquitin-specific protease related disease or disorder and increased prepulse inhibition. As such, according to the Examiner, the transgenic mice of the present invention have no specific and credible utility.

The Applicant contends that the transgenic mice do have a specific and credible utility. As currently amended, the claims are drawn to a transgenic mouse whose genome comprises a disruption in a nucleotide sequence comprising SEQ ID NO:1, which mice exhibit increased prepulse inhibition. The claims further encompass cells isolated from the same mice, and methods of producing the same mice. As disruption of the nucleotide sequence leads to a phenotype of increased prepulse inhibition, as disclosed in the instant specification, one of ordinary skill in the art would conclude that antagonizing or decreasing the expression of this nucleotide sequence ameliorates a symptom associated with schizophrenia.

Applicant asserts that the transgenic mice whose genomes comprise a disruption in a nucleotide sequence comprising SEQ ID NO:1 are useful for the screening of agents intended to treat schizophrenia or affect prepulse inhibition. It would be within the knowledge of the skilled artisan that these mice can be used to test known compounds used to treat schizophrenia or related stimulus processing disorders, which compounds target a protein or system other than the nucleotide sequence comprising SEQ ID NO:1. In particular, the transgenic mice could be used to screen such agents to determine whether these compounds would act additively or synergistically with an agent that targets the nucleotide sequence comprising SEQ ID NO:1 to affect prepulse inhibition or stimulus processing. In addition, the transgenic mice would be valuable for screening test compounds for the treatment of schizophrenia, which compounds do not target a nucleotide sequence comprising SEQ ID NO:1 for the same purpose. Further, since a disruption of the nucleotide sequence is present in the transgenic mice, the transgenic mice may be used to test agents that target the nucleotide sequence. This method would comprise administering the test agent to the transgenic mouse and a wild-type mouse, and determining whether the agents affect prepulse inhibition in the mice, wherein if the agents affect prepulse inhibition in the wild-type mouse and not the transgenic mouse, the agent would be identified as an agent for treating schizophrenia which targets the nucleotide sequence comprising SEQ ID NO:1.

Applicant contends that the usefulness of the transgenic mice as encompassed by the currently amended claims discussed above would be well within the skill of the art of gene targeting and transgenic mice. As such, the Applicant believes that the rejection under 35 U.S.C. § 101 is no longer relevant, and requests withdrawal of the rejection.

B. Rejection under 35 U.S.C. § 112, first paragraph

1. Claims 26-40 were rejected under 35 U.S.C. § 112, first paragraph, because the claimed invention is allegedly not supported by either a credible asserted utility or a well established utility for the reasons set forth in the rejection under 35 U.S.C. § 101 above. Applicant respectfully traverses the rejection. However, in light of the remarks set forth above, Applicant contends that the rejection is no longer relevant, and requests withdrawal of the rejection.

2. The Examiner further rejected claims 26-40 under 35 U.S.C. § 112, first paragraph, asserting that the specification does not enable any person skilled the art to make and use the invention commensurate in scope with these claims.

Specifically, the Examiner states that the claims as previously submitted encompass a transgenic mouse whose genome comprises a disruption in a target gene, wherein the target gene is capable of homologous recombination with a nucleotide sequence homologous to SEQ ID NO:1, wherein the mouse exhibits a phenotype of increased prepulse inhibition. The Examiner further asserts that these claims as written are very broad with regard to target genes as they now encompass disruption of nucleotide sequences encoding proteins which have different structures and functions, and can be interpreted to read on nucleotide sequences that share homology of a single nucleotide base. The Applicant respectfully disagrees, and in particular argues that the claims do not broadly read on disruption of nucleotide sequences that share homology of a single nucleotide base. The Applicant submits that one of ordinary skill in the art of gene targeting would know the significant degree of homology required between two sequences for homologous recombination to occur, and would not interpret the claims to read upon any target gene, or on target genes which encode proteins with different structures and functions.

The Applicant submits that the specification provides adequate guidance for the production of a transgenic mouse whose genome comprises a disruption in the target gene as claimed. However, the Applicant has amended claims 26, 31 and 34, and cancelled claims 37-40. The amended claims are drawn to a transgenic mouse whose genome comprises a disruption in a

nucleotide sequence comprising SEQ ID NO:1, which mouse exhibits increased prepulse inhibition, methods of making the same and cells isolated from the same. Applicant submits that the specification provides sufficient enabling disclosure for the transgenic mice and cells as recited in currently amended claims 26-36.

As this rejection under 35 U.S.C. § 112, first paragraph, of claims 26-40 is no longer relevant as a result of the cancellation of claims 37-40 and the instant amendment, and claims 26-36 as currently amended are fully enabled by the teachings of the specification as noted above, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

3. The Examiner has also rejected claims 26-40 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. The Examiner specifically alleges that the previously added claims have added new matter not supported by the specification as filed.

The Examiner states that the specification provides no implicit or explicit support for the context of the disruption of a target gene that is capable of homologous recombination with a nucleotide sequence homologous to SEQ ID NO:1. According to the Examiner, the specification only provides support for disruption of a target gene that comprises the nucleotide sequence set forth in SEQ ID NO:1 that results in a phenotype of increased prepulse inhibition in a transgenic mouse.

The Applicant respectfully disagrees with this conclusion for the reasons stated above. However, the Applicant has amended claims 26-36 and cancelled claims 37-40. Claims 26-36, as amended, do not constitute new matter, and are fully supported by the instant specification. As such, the Applicant believes this rejection under 35 U.S.C. § 112, first paragraph, is no longer relevant, and respectfully requests withdrawal of the rejection.

4. The Examiner has further rejected claims 26-40 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed.

In particular, the Examiner has alleged that the specification has not disclosed target genes other than a nucleotide sequence comprising SEQ ID NO:1, embraced by the claims, within the genus of target genes that are capable of homologous recombination with a nucleotide sequence

homologous to SEQ ID NO:1. The Examiner, in the rejection, asserts that there is no relationship between the structure of the nucleotide sequence set forth in SEQ ID NO:1 and the other target genes embraced by the claims that would provide any reliable information about the structure of other target genes within the genus. Further, the Examiner states that there is no evidence of record that would indicate that any of the other target genes embraced by the claims, which when disrupted in a transgenic mouse would result in a phenotype of increased prepulse inhibition.

The Applicant respectfully disagrees with the Examiner's conclusions. However, in light of the amendment to the claims, Applicant contends that the specification would fully enable one of ordinary skill in the art to make and use the invention as currently claimed. As such, the rejection under 35 U.S.C. § 112, first paragraph, is no longer relevant, and Applicant respectfully requests its withdrawal.

It is believed that the claims are in condition for allowance, and notice to that effect is respectfully requested. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1271 under Order No. R-456.

Respectfully submitted,

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Enclosure